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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/597,179	06/20/2000	Maura Rooney	BSP2102US02	5883

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EXAMINER

FOREMAN, JONATHAN M

ART UNIT PAPER NUMBER

3736

DATE MAILED: 12/30/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/597,179

Applicant(s)

ROONEY ET AL.

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22, 25, 26, 28-30 and 32-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22, 25, 26, 28-30 and 32-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 June 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 22 6) ☐ Other: _____

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed 10/2/03 complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file, and the information referred to therein has been considered by the examiner as to the merits.

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the coating, the rectangular cross-section and the multifilar wire of claims 34 – 37, 39 and 40 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 24 – 26, 28, 34, 35, 37 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,067,489 to Lind (cited by Applicant).

4. In reference to claims 24 – 26, 28, 34, 35, 37 and 38, Lind discloses a guidewire including an elongate core (12') composed of a nickel-titanium alloy (Col. 3, lines 66 – 68) including a length, a proximal and distal portion; a continuous, unitary coil composed of a second material and that

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surrounds the length of the core and extends distal of the distal portion of the core (Col. 4, lines 45 – 48); and a tip composed of a polymeric material (Col. 3, lines 30 - 53) and extending from a distal portion of the coil. The second material comprises stainless steel (Col. 2, lines 65 – 68). Lind discloses a lubricious coating and the coil comprising a rectangular cross-section and a circular cross-section (Col. 2, lines 56 – 63).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 22, 25, 26, 28, 30, 33 – 35 and 38 – 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,139,640 to Rost et al. in view of U.S. Patent No. 5,067,489 to Lind.

7. In regards to claims 22, 25, 26, 28, 30, 33 – 35 and 38 – 40, Rost et al. discloses a guidewire including an elongate core (60) composed of a nickel-titanium alloy (Col. 9, lines 5 - 16) including a length, a proximal and distal portion and a continuous, unitary coil (62) composed of a second material and that surrounds the length of the core and extends distal of the distal portion of the core. The second material comprises stainless steel (Col. 9, lines 5 – 16). The distal portion of the core is tapered (Col. 7, lines 20 – 22). Rost et al. discloses the coil having a pitch that varies at least once (Col. 6, lines 46 – 47), having a circular cross-section and being formed of a cross-wound multifilar wire (Col. 6, lines 55 – 60). Rost et al. discloses the coil comprising a lubricious coating (Col. 9, lines 17 – 24). Rost et al. discloses a traumatic distal tip (40) of braze, solder, or adhesives

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for attaching coil and core components (Col. 6, lines 50 – 54). However, Rost et al. fails to disclose the tip being composed of a polymeric material. Lind discloses an atraumatic distal tip being composed of a polymeric material (Col. 3, lines 30 – 53). It would have been obvious to one having ordinary skill in the art to modify the tip as disclosed by Rost et al. to be composed of a polymeric material as taught by Lind in order to minimize tissue trauma upon insertion into the body.

8. Claims 22, 25, 26, 28, 30, 34, 35, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,245,030 to DuBois et al. in view of U.S. Patent No. 6,106,485 to McMahon.

In regards to claims 22, 25, 26, 28, 30, 34, 35, 37 and 38, DuBois et al. discloses a guidewire including an elongate core (12) composed of a nickel-titanium alloy (Col. 3, lines 56 - 61) including a length, a proximal and distal portion and a continuous, unitary coil (14) composed of a second material (Col. 3, lines 20 – 22) and that surrounds the length of the core and extends distal of the distal portion of the core. The second material comprises stainless steel (Col. 3, lines 20 - 22). The distal portion of the core (26) is tapered. DuBois et al. discloses the coil having a rectangular cross-section or a circular cross-section (Col. 5, lines 10 – 15). DuBois et al. discloses the coil comprising a lubricious coating (Col. 5, line 63 – Col. 6, line 10). DuBois et al. discloses a distal tip (18) but fails to disclose the tip being composed of a polymeric material. McMahon teaches a guidewire having a polymeric tip (20) for preventing trauma to the patient upon insertion into the body. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the tip as disclosed by DuBois et al. to be composed of a polymeric material as taught by McMahon in order to prevent trauma during insertion.

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9. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,067,489 to Lind as applied to claim 22 above, and further in view of U.S. Patent No. 5,947,940 to Beisel.

In regards to claim 29, Lind fails to disclose using a precipitation hardened alloy as the coil material. Beisel discloses a precipitation hardened alloy as the coil material for aiding guidewire insertion into a patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the guidewire of Lind to include the precipitation hardened alloy as taught by Beisel to increase the coil stiffness and enhance torqueability. Furthermore, the selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

10. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,067,489 to Lind as applied to claim 22 above, and further in view of U.S. Patent No. 5,885,227 to Finlayson.

In regards to claim 32, Lind discloses a polymeric tip (Col. 3, lines 37 – 38), but fails to disclose the tip including radio-opaque material. Finlayson discloses a guidewire having a polymeric tip (20) that includes radio-opaque material (Col. 3, lines 29 – 35). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the polymeric tip as disclosed by Lind to include radio-opaque material as taught by Finlayson to allow the tip of the guidewire to be seen with an imaging device while performing a medical procedure.

11. Claim 36 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,067,489 to Lind as applied to claim 34 above, and further in view of U.S. Patent No. 5,997,517 to Whitbourne.

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In regards to claim 36, Lind discloses a polymeric coating, but fails to disclose the coating being colored. Whitbourne teaches the use of a colored coating with various medical devices such as guidewires to enhance the performance of the devices (Col. 4, lines 2 – 11). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the guidewire as disclosed by Lind to include a colored coating as taught by Whitbourne to enhance the performance of the guidewire by assisting in the identification of the guidewire.

Response to Arguments

12. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703)-305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (703)308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703)-872-9306 for regular communications and (703)-872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0858.



JMLF
December 29, 2003



ERIC F. WINAKUR
PRIMARY EXAMINER